

REMARKS

Review and reconsideration of the non-final Office Action mailed December 16, 2008 (hereinafter "Office Action"), is respectfully requested in view of the preceding amendments and the following remarks. Although no fees are believed due, the Commissioner is hereby authorized to charge any deficiency or credit any surplus to Deposit Account No. 14-1437.

At the time of the Office Action, claims 1-4 and 6-10 were pending, with claims 1-4 and 6-9 being drawn to an elected invention. In the Office Action, all claims were rejected under 35 U.S.C. §103(a). By this Amendment, claims 1, 2, 4, 7 and 9 are amended, claims 3 and 6 are cancelled, and claims 11-13 are added.

The amendments presented herein have been made solely to expedite prosecution of the instant application to allowance and should not be construed as an indication of Applicant's agreement with or acquiescence to the Examiner's position. Accordingly, Applicants expressly maintain the right to pursue broader subject matter through subsequent amendments, continuation or divisional applications, reexamination or reissue proceedings, and all other available means. The rejections are addressed in more detail below.

Claim Amendments

In the Office Action, claim 1 is amended to incorporate the subject matter of cancelled claims 4 and 6. Support for the remaining claim amendments and new claims can be found throughout the specification. *See, e.g.,* Specification, Examples. No new matter is added.

Claim Rejections - 35 U.S.C. § 103

In the Office Action, claims 1-4 and 6-9 were rejected under 35 U.S.C. §103(a) as being unpatentable over U.S. Patent No. 6,471,983 issued to Veeger *et al.* (hereafter "Veeger") as evidenced by Kraton IR 401 brochure of record in view of U.S. Patent Application Publication 2003/00444469 filed by Viladot (hereinafter "Viladot"). The Office Action asserts that Veeger teaches all elements of the claims, except for a modified clay. However, the Office Action asserts that Viiadol teaches skin care compositions that comprise thickeners including xanthan

gum, polyacrylate polymers, disteardimonium hectorite (BENTONE), etc. In order to make the instant rejection, the Office Action also asserts that latex Kraton, *i.e.*, emulsion polymerized KRATON in an aqueous suspension, is equivalent to the claimed polyisoprene, which has been comminuted and depolymerized. However, no reference has been cited to show that the claimed polyisoprene particles produced by comminuting and depolymerizing have been used in a cosmetic composition. Applicants respectfully disagree with the conclusion of obviousness.

Prior to addressing the cited art, Applicants wish to review the claimed cosmetic composition as set forth in amendment claim 1, which recites:

1. (Currently Amended) A cosmetic composition, suitable for application to facial skin, lips and eyelashes, consisting of:
from 2 to 25% of a polyisoprene obtainable by the process comprising the steps of a) comminuting a solid polyisoprene with a molecular weight of between 100,000 and 4,000,000 and b) depolymerising the comminuted solid polyisoprene of step a) to a molecular weight within the above range;
from 0.05 to 20% of disteardimonium hectorite oleophylic modified smectite clay;
from 1.1 to 90 % of isododecane an aliphatic hydrocarbon with 12-22 carbon atoms;
the balance comprising conventional cosmetic excipients, colourants and additives, all percentages being by weight of the final composition,
wherein said cosmetic composition is an anhydrous composition.

The claimed cosmetic composition suitable for application to facial skin, lips and eyelashes is an anhydrous composition that consists of 2 to 25 wt-% polyisoprene produced by a comminuting and depolymerizing process, 0.05 to 20 wt-% disteardimonium hectorite, 1.1 to 90 wt-% isododecane, and conventional cosmetic excipients, colourants and additives. The polyisoprene is produced by step a), which comprises comminuting, *i.e.*, crushing or grinding, a solid polyisoprene with a molecular weight between 100,000 and 4,000,000, and step b), which comprises depolymerising the comminuted solid isoprene of step a). As will be evident, the particles produced by a comminuting process will have a substantially rougher surface morphology and more irregular shape than the spherical particles produced by emulsion polymerization, such as the KRATON IR-401 latex disclosed by Veegee. It is believed that, when combined with the other claimed ingredients, the rough surface morphology and irregular

shape of the comminuted polyisoprene particles contributes to the properties of the claimed cosmetic compositions, which can be applied to the facial skin, the lips and the eyelashes to produce an unexpectedly stable, homogeneous, and long-lasting film.

Cosmetic products for make-up of face, lips, eyelashes, etc., often suffer from the drawback that, when they come into contact with fingers or clothing, they tend to smudge or soil these surface. In addition, in some cases the make-up can also appear to be not homogeneous.

Therefore, in order to avoid these problems cosmetic products suitable for application to facial skin, lips and eyelashes have to be endowed with the following properties: be stable, have high film-forming properties and provide for the deposition of a homogeneous, long lasting film onto the facial skin, the lips and the eyelashes.

Applicants respectfully submit that the combination of the cited references does not render the claimed cosmetic composition obvious because (1) the rejection fails to disclose each element of the claims, including the claimed isoprene particles produced by a comminuting and depolymerizing process, (2) the rejection relies on the assumption that several ingredients are interchangeable or equivalent when, in fact, they are not, and (3) because the claimed combination of ingredients produces unexpected results that are neither disclosed nor suggested by the cited references.

In order to demonstrated the unexpected results obtained by the claimed cosmetic composition, Applicants submit the attached Declaration Under 37 C.F.R. §1.132 by co-inventor Giuseppe Maio (hereinafter “Maio Declaration”). As explained by Mr. Maio:

During my experiments, I have surprising[ly] found that the combination of 1) a polyisoprene (from 2 to 25% (w/w)) obtainable by the process comprising the steps of a) comminuting a solid polyisoprene with a molecular weight of between 100,000 and 4,000,000 and b) depolymerising the comminuted solid polyisoprene of step a) to a molecular weight within the above range, 2) disteardimonium hectorite (0.05 to 20% (w/w)) and 3) isododecane (from 1.1 to 90% (w/w)), the balance comprising conventional cosmetic excipients, colorants and additives, is critical in order to achieve an anhydrous cosmetic composition which is stable and provides for the deposition of a homogeneous, long lasting film onto the facial skin, the lips and the eyelashes.

Maio Declaration, Section 4.

Mr. Maio conducted extensive experimentation in order to arrive at the claimed cosmetic composition. From all of the compositions tested in these experiments, Mr. Maio has selected the following three in order to demonstrate the dramatic and unexpected improvements produced using the claimed ingredients. While additional details of compositions REM 513.32, REM 513.33, and REM 5123.34 can be found in the Maio Declaration (section 4), a summary of these compositions is found below:

	REM 513.32	REM 513.33	REM 513.34
Polyisoprene	10.0 wt-% comminuted KRATON IR 310	10.0 wt-% comminuted KRATON IR 310	15.0 wt-% polyisoprene <u>latex</u> (KRATON IR401B)
Disteardimonium hectorite (BENTONE 38V)	6.0 wt-%	0.0 wt-%	6.0 wt-%
Isododecane	79.0 wt-%	85.0 wt-%	73.5 wt-%
Colourants	5 wt-%	5.0 wt-%	5 wt-%

The properties of these compositions were as follows:

REM 513.32

Aspect: Creamy fluid stable product endowed with high long lasting film properties.

Drying time after application: 3 minutes

REM 513.33

Aspect: Liquid unstable product, after 2 hours from its preparation the product shows an evident color phase separation and thus making the product not applicable.

Drying time after forced application; 6 minutes

RE 513.34

Aspect: Doughy unstable product, visually unhomogeneous and thus making the product not applicable.

Drying time after forced application: 10 minutes

In order to evaluate the aspect and the drying time, the unstable comparative products, *i.e.*, REM 513.33 and REM 513.34, have been made homogeneous. *See* Maio Declaration, Section 4. Each of the compositions was evaluated using a transferability resistance assay and a saliva resistance assay.

The results of the Transferability Resistance Assay after 10 wipes were as follows:

REM 513.32	REM 513.33	REM 513.34
No transfer	Very poor transfer	Poor transfer

As noted by Mr. Maio:

[T]he films of the comparable product REM 513.34 deposited on the paper were visually unhomogeneous. As far as the comparable product REM 513.34 is concerned, it showed very evident colour streaks and its deposited film was easily removed by means of a finger wipe.

Maio Declaration, Section 4.

The results of the Saliva Resistance Assay after 5 wipes, were as follows:

REM 513.32	REM 513.33	REM 513.34
Clean tampon, no colour transfer	Slightly colour dirty tampon, slight ring	Slightly colour dirty tampon, slight ring

Maio Declaration, Section 4.

In evaluating the experimental data, Mr. Maio explains:

From the above experimental data, it is evident that the combinative effect of the presence of the three specific components selected, *i.e.*, 1) the polyisoprene obtainable by the process comprising the steps of a) comminuting a solid polyisoprene with a molecular weight of between 100,000 and 4,000,000 and b) depolymerising the comminuted solid polyisoprene of step a) to a molecular weight within the above range, 2) disteardimonium hectorite and 3) isododecane (REM 513.32) is essential in order to achieve a stable anhydrous cosmetic composition endowed with high film-forming property, which is easy to use and stable over a medium-long term and which provides for the deposition of a homogeneous long lasting film on the facial skin, lips and eyelashes.

Indeed, as shown from the above data, only the invention product: (REM 513.32) is endowed with a homogeneous creamy fluid aspect, has good film-forming property and a short drying time after application which makes it easy to use.

Furthermore, from the data shown above, it is also evident that the invention product (REM 513.32) is also a stable product.

On the contrary, all the comparative products (REM 513.33 and REM 513.34) are unstable and with an unhomogeneous aspect and therefore unsuitable for the preparation of a cosmetic composition for application to facial skin, lips and eyelashes.
Maio Declaration, Section 5.

With this testing as background, it is Applicants position that the claimed cosmetic composition is not disclosed or suggested by any combination of the cited art and that the claimed cosmetic composition exhibits unexpected properties that are not disclosed or suggested by the cited references.

Turning now to U.S. Patent No. 6,471,983, which discloses a skin application agent containing a polyisoprene latex. In particular, in all the Examples of U.S. Patent No. 6,471,983, Kraton IR 401 is employed as polyisoprene latex. Such a latex would include spherical particles of polyisoprene, produced by emulsion polymerization, in an aqueous suspension. In contrast, the claimed cosmetic composition employs polyisoprene particles obtained by a process including comminuting and depolymerizing processes.

The absence of a polyisoprene obtainable by the process comprising the steps of a) comminuting a solid polyisoprene with a molecular weight of between 100,000 and 4,000,000 and b) depolymerising the comminuted solid polyisoprene of step a) to a molecular weight within the above range, makes the product of U.S. Patent No. 6,471,983 unsuitable for the preparation of the cosmetic composition of the present invention which is stable, has high film forming property and is endowed with a homogenous aspect. See Maio Declaration, Section 6.

Mr. Maio provided proof of the unsuitability of the product of U.S. Patent No. 6,371,983 with the experimental data of the analogous comparison product REM 513.34. As explained above, it is believed that the unique topology and irregular shape of the comminuted particles causes the polyisoprene particles to interact with the remaining ingredients to produce the unexpected properties of the claimed cosmetic compositions. See Maio Declaration, Section 6.

Moreover, in U.S. Patent No. 6,471,983, no specific mention of disteardimonium hectorite is made among the thickeners. As far as U.S. Patent Application Publication No. 2003/0044469 is concerned, it relates to skin care compositions containing microcapsules prepared by the process comprising: (a) providing an oil-in-water emulsion prepared by combining an aqueous preparation of components selected from the group consisting of retinol and retinolic acid with an oil component in the presence of an emulsifier; (b) combining the emulsion and an aqueous solution of an anionic polymer to form a matrix; (c) contacting the matrix with an aqueous chitosan solution such that membrane-encapsulated products are formed in an aqueous phase; and (d) separating the products from the aqueous phase. *See* Maio Declaration, Section 6. In contrast, the cosmetic composition of the present invention is an anhydrous composition.

Furthermore, no polyisoprene has been mentioned in the skin care composition of U.S. Patent Application Publication No. 2003/0044469 and no hint to select the specific disteardimonium hectorite has been made by U.S. Patent Application Publication No. 2003/0044469. *See* Maio Declaration, Section 6. Indeed, in the skin care composition of U.S. Patent Application Publication No. 2003/0044469, disteardimonium hectorite is embedded in a long list of other thickeners and only in the form of a mixture with cyclopentasiloxane and propylene carbonate, *i.e.*, the product Bentone® Gel VS-5PC (Rheox) (U.S. Patent Application Publication No. 2003/0044469, paragraph [0058]). *See* Maio Declaration, Section 6.

In fact, it should be noted in the o/w emulsion system hydrophilic of U.S. Patent Application Publication No. 2003/0044469, thickeners including, for example, xanthan gum and polyacrylates are suitable to be employed. However, hydrophobic thickener such as disteardimonium hectorite can be used in the o/w emulsion system of U.S. Patent Application Publication No. 2003/0044469 only in the form of a mixture with cyclopentasiloxane and propylene carbonate and in the presence of an emulsifier, such as cetearyl glucosides (and) cetearyl alcohol, *i.e.*, the EMULGADE® PL 68/50 product. However, the disteardimonium hectorite alone is not capable to be dissolved in such oil-in-water emulsion (*see* U.S. Patent Application Publication No. 2003/0044469, Tables 1 and 2, Enclosure A1). *See* Maio Declaration, Section 6.

Therefore, the disteardimonium hectorite used in the claimed cosmetic composition is not a functionally equivalent thickener to thickeners, such as xanthan gum and polyacrylates, because the disteardimonium hectorite is distinguished from such species essentially for its hydrophobic nature and thus its affinity for anhydrous systems. *See* Maio Declaration, Section 6.

As a further proof that a specific selection of the disteardimonium hectorite has been made, Applicants note that not all BENTONE products are suitable to be used in an anhydrous cosmetic composition. Indeed, for example, Bentone EW (*i.e.*, hectorite) is a rheological additive for the aqueous phase of cosmetics and therefore is unsuitable to be employed in the claimed anhydrous cosmetic composition (*see* Enclosed Product Data Sheet). *See* Maio Declaration, Section 6.

Moreover, the Maio Declaration provides evidence that the absence of the specific disteardimonium hectorite of the invention leads to an unstable, unhomogeneous product (see REM 513.33) that is not useful for producing a homogeneous, long-lasting film for facial skin, lips, and eyelashes. *See* Maio Declaration, Section 6.

It is therefore clear that neither U.S. Patent No. 6,471,963 nor U.S. Patent Application Publication No. 2003/0044469 suggest to select the three specific components in the claimed amounts to produce the unexpected properties shown in the specification and the Maio Declaration. The claimed compositions contain: 1) polyisoprene obtainable by the process comprising the steps of a) comminuting a solid polyisoprene with a molecular weight of between 100,000 and 4,000,000 and b) depolymerising the comminuted solid polyisoprene of step a) to a molecular weight within the above range, 2) disteardimonium hectorite, and 3) isododecane, as essential elements in order to achieve a stable anhydrous cosmetic composition having high film-forming property and which provides for the deposition of a homogeneous, long lasting film on the facial skin, lips and eyelashes. This is demonstrated by the evidence supplied by the Maio Declaration. *See* Maio Declaration, Sections 4-6.

In the instant application, the claimed cosmetic composition unexpectedly demonstrates superior properties by depositing a homogenous, long-lasting film on the facial skin, the lips and the eyelashes. The specific mixture of ingredients can only be produced by taking the cited references and (i) assuming polysioprene particles produced by comminuting a solid

polyisoprene and depolymerizing the polyisoprene is the same as emulsion polymerized polyisoprene polymers (which is an erroneous assumption), and (ii) assuming that a hydrophilic disteardimonium hectorite mixture utilized in an oil-in-water emulsion is equivalent anhydrous composition containing disteardimonium hectorite. Through the data submitted herewith, Applicants have demonstrated that there is a substantial functional difference between spherical isoprene particles produced by emulsion polymerization and the claimed irregularly shaped isoprene particles having a rough surface morphology. Furthermore, the rejection fails to identify any reference disclosing irregularly shaped isoprene particles produced by a combination of comminuting and depolymerizing, much less the use of such particles in a cosmetic composition. Thus, it is Applicants' position that the cited references fail to establish a *prima facie* case of obviousness.

Regardless of whether a *prima facie* case of obviousness has been established, Applicants note that the Federal Circuit has held that evidence that a compound or composition possesses superior and unexpected properties in one of a spectrum of common properties can be sufficient to rebut a *prima facie* case of obviousness. See *In re Chupp*, 816 F.2d 643, 646 (Fed. Cir. 1987); MPEP 716.02(a).II. & 2145. In *In re Chupp*, the claims at issue were drawn to a compound for use as a selective herbicide with unexpectedly superior herbicidal efficacy for soybeans and corn, but average herbicidal results for other crops. See *id.*, at 644. The prior art was a homolog of the claimed compound that differed from the claimed compound by a single methylene group (C=C), and was disclosed as being a selective herbicide for crops generally. Thus, the difference between the claimed compound and the prior art was a single methylene group and an unexpected improvement in herbicidal efficacy that was limited to two crops.

The Court noted that the claimed compound's "superior activity in corn and soybeans is a new and unexpected property," *In re Chupp*, 816 F.2d at 645. The Commissioner argued that the claimed compound was similar to the prior art and provided average selective herbicidal activity for many crops and poor herbicidal activity for others. *The Federal Circuit concluded that the fact that a compound or composition possesses superior and unexpected properties in one of a spectrum of common properties was sufficient to rebut a prima facie case of obviousness. See id.*, at 646.

The Federal Circuit nicely summarizes cases in this line by stating "*Obviousness cannot be predicated on what is not known at the time an invention is made,*" *In re Rijckaert*, 9 F.2d 1531, 1534 (Fed. Cir. 1993). In the instant case, it simply was not known that the claimed combination of the ingredients, in the claimed amounts, would unexpectedly exhibit superior properties by depositing a homogenous, long-lasting film on the facial skin, the lips and the eyelashes. Accordingly, Applicants respectfully submit that the evidence of unexpected results submitted herewith is sufficient to overcome a *prima facie* case of obviousness, if one has been established (which Applicants would argue it has not).

Finally, Applicants respectfully submit that the issues raised with respect to the prior declaration of Mr. Maio are not supported by the MPEP. When considering unexpected results, it is clear that the MPEP only requires that a Declaration or evidence in the specification address the closest known prior art, not what is suggested by combinations of the prior art. See MPEP 716.02(e).III. In fact, the MPEP expressly teaches that:

Although evidence of unexpected results must compare the claimed invention with the closest prior art, *applicant is not required to compare the claimed invention with subject matter that does not exist in the prior art*. *In re Geiger*, 815 F.2d 686, 689, 2 USPQ2d 1276, 1279 (Fed. Cir. 1987) (Newman, J., concurring) (Evidence rebutted *prima facie* case by comparing claimed invention with the most relevant prior art. Note that the majority held the Office failed to establish a *prima facie* case of obviousness.); *In re Chapman*, 357 F.2d 418, 148 USPQ 711 (CCPA 1966) (*Requiring applicant to compare claimed invention with polymer suggested by the combination of references relied upon in the rejection of the claimed invention under 35 U.S.C. 103 "would be requiring comparison of the results of the invention with the results of the invention."* 357 F.2d at 422, 148 USPQ at 714.).

MPEP 716.02(e).III. (emphasis added).

With this clarification, Applicants respectfully submit that the data submitted in the Maio Declaration is sufficient to demonstrate an unexpected result based on the disclosure of Veeger (U.S. Patent No. 6,471,983), which (though requiring substantial modification) appears to be the closest of the cited references. Applicants respectfully request reconsideration of the instant rejection in view of the preceding arguments, the Maio Declaration, and the relevant case law


discussed herien. Accordingly, Applicants respectfully request that the rejection based on the combination of Veeger, Vildot and the KRATON IR401 borchure be withdrawn.

Conclusion

For at least the reasons set forth above, the independent claims are believed to be allowable. In addition, the dependant claims are believed to be allowable due to their dependence on an allowable base claim and for further features recited therein. The application is believed to be in condition for immediate allowance. If any issues remain outstanding, Applicant invites the Examiner to call the undersigned, Greg Lefkowitz (direct line 561-838-5229 x228), if it is believed that a telephone interview would expedite the prosecution of the application to an allowance.

Respectfully submitted,
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